

B3
36. (Amended) A coated implant comprising an implant, a first coating, and a second coating, said first coating comprising magnesium ions, calcium ions, and phosphate ions and wherein said coating induces formation of bone cells from progenitor cells, wherein a second coating is applied to said implant after said first coating, said second coating comprising calcium and phosphate ions.

B4
37. (New) The coated implant of claim 37, wherein the second coating comprising calcium and phosphate ions further comprises octacalcium phosphate. *dep. on self*
no basis

38. (New) The coated implant of claim 27 wherein the coating comprises octacalcium phosphate.

I. Status of the Application

Claims 27-36 are pending in the application. Claims 27, 28, and 33 stand rejected under 35 U.S.C. 102(b) as anticipated by Kokubo *et al.* (U.S.P.N. 5,068,122). Claims 27, 28, and 32 stand rejected under 35 U.S.C. 102(e) as anticipated by Li (U.S.P.N. 6,139,585). Claims 27-33 and 36 stand rejected under 35 U.S.C. 102(e) as anticipated by Leitao (U.S.P.N. 6,069,295). Claims 34 and 35 stand rejected under 35 U.S.C. 103(a) as unpatentable over Leitao. (U.S.P.N. 6,069,295).

The Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. The reference to the claimed coating inducing formation of bone cells from progenitor cells is found at page 18 lines 14-27. The reference to octacalcium phosphate is

found at page 16 lines 24-35. Claim 30 was amended to correct an inadvertent typographical error. No new matter is added by the amendments to the claims.

Applicants respectfully request entry and consideration of the foregoing amendments which are intended to place this case in condition for allowance.

II. Claims 27, 28, and 33 are novel over Kokubo et al.

Applicants' invention is directed to a novel coated implant formed using an approach which approximates physiological fluids, temperature and pH during bone formation. The novel coating, while including components characteristic of bone-like apatite, is further characterized by its ability to induce formation of bone cells from progenitor cells due to a high density of nucleation defining a surface morphology and crystal orientation.

At page 2, paragraph 2 of the present Office Action, claims 27, 28 and 33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kokubo *et al.* The Examiner asserts that Kokubo *et al.* teaches "forming a hydroxyapatite coating on metallic or organic substrates by soaking the substrate in an aqueous solution containing constituent ions of hydroxyapatite (abstract)." The Examiner further asserts that the constituent ions "include calcium, phosphate and magnesium (see Table 2) as required by Applicant." Applicants respectfully traverse the present rejection based on the amended claims now presented.

Applicants' claims include a coating which induces formation of bone cells from progenitor cells. Kokubo, which teaches a bone-like bioactive apatite coating produced by eluting ions from glass into a saturated or supersaturated aqueous solution to cause the ions in solution to precipitate

— Same coat, must inherently do same w/ glass
the coating of app does not have limitation not present in claims
— intended use of coating in product
3 claim not relevant?

onto a substrate located near the glass, does not teach that its coating has a surface morphology which induces formation of bone cells from progenitor cells.

Accordingly, Kokubo fails to teach all of applicants' claim limitations.

III. Claims 27, 28, and 32 are novel over Li

At page 2, paragraph 3 of the present Office Action, claims 27, 28 and 32 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Li. The Examiner asserts that “Li teaches a coated implant wherein the coating comprises calcium ions, phosphate ions, magnesium ions and carbonate ions (abstract and claims).” The Examiner further asserts that the “implant substrate may be metal, ceramic, or polymer (col. 4, lines 59).” Applicants respectfully traverse the present rejection based on the amended claims now presented.

Applicants' claims include a coating which induces formation of bone cells from progenitor cells. Li, which teaches a bioactive nonhydroxyl containing coating that encourages bone ingrowth produced by an immersion method, does not teach that its coating has a surface morphology which induces formation of bone cells from progenitor cells.

Accordingly, Li fails to teach all of applicants' claim limitations.

IV. Claims 27-33, and 36 are novel over Leitao

At page 3, paragraph 4 of the present Office Action, claims 27-33 and 36 stand rejected under 35 U.S.C. 102(e) as being anticipated by Leitao. The Examiner asserts that “Leitao teaches coating a metal or ceramic substrate with an amorphous calcium phosphate layer, which can be made from a combination of calcium and phosphate ions, together with hydroxide, magnesium, and/or chloride

ions (col. 2, lines 20-25). The calcium phosphate layer may also form hydroxyapatite (col. 5, line 13).” The Examiner further asserts that “Leitao teaches pre-treatment of the substrate, prior to coating of said implant, using a chemical surface treatment, such as treatment with a strong mineral acid, or a mechanical surface treatment, such as sanding or scoring (col. 2, lines 40-50).” In specific regard to claim 36, the Examiner asserts that “Leitao teaches pre-coating with the above coating material and then placing the implant into the body where an additional calcium phosphate layer is formed on the implant in vivo (col. 3, lines 1-6).” Applicants respectfully traverse the present rejection based on the amended claims now presented.

Applicants' claims include a coating which induces formation of bone cells from progenitor cells. Leitao, which teaches a roughened implant surface with a coating of calcium phosphate thereon to enhance bone formation, does not teach that its coating has a surface morphology which induces formation of bone cells from progenitor cells.

Accordingly, Leitao fails to teach all of applicants' claim limitations.

V. Claims 34 and 35 are not obvious over Leitao

At page 3, paragraph 5 of the present Office Action, claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leitao. The Examiner asserts that the Leitao reference additionally “teaches that the calcium phosphate layer is preferably 1-50 microns (col. 2, line 19), overlapping the ranges set forth by the Applicant.” The Examiner further asserts that “[o]verlapping ranges are *prima facie* evidence of obviousness.” Applicants respectfully traverse the present rejection based on the amended claims now presented.

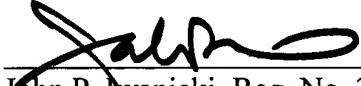
Applicants' claims include a coating which induces formation of bone cells from progenitor cells. Leitao, which teaches a roughened implant surface with a coating of calcium phosphate thereon to enhance bone formation, does not teach that its coating has a surface morphology which induces formation of bone cells from progenitor cells. Since Leitao fails to teach or suggest all of applicants' claim limitations, applicants respectfully request the Examiner withdraw the obviousness rejection.

VI. CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7111.

Respectfully submitted,

Dated: October 22, 2001


John P. Iwanicki, Reg. No. 34,628
BANNER & WITCOFF, LTD.
28 States Street, 28th Floor
Boston, MA 02109
617-227-7111